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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/729,086 | 12/05/2003 | Fred H. Burbank | R0367-02501 | 8823 |

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| EXAMINER | |
|---|---|
| DRYDEN, MATTHEW DUTTON | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/729,086 | BURBANK ET AL. | |
| | Examiner | Art Unit | |
| | Matthew D. Dryden | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-54 and 66-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48, 51-54, 66-70, 73-76* is/are rejected.

7)☒ Claim(s) *49,50,71 and 72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/5/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to applicant's amendment filed on December 22, 2005.

### *Priority*

Examiner acknowledges the response to priority and the priority date given to the current application is that of Application No. 09/727,112, which is November 29, 2000.

### *Information Disclosure Statement*

Examiner acknowledges the submitted foreign patent documents and the non-patent literature publications and have been considered.

### *Claim Objections*

Examiner acknowledges the changes to the claims to overcome the claim objections.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 37 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,679,851. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim the same device.

Claims 38 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,679,851 in view of Gough et al (5683384). The claims of the cited patent are similar to those of the current application except for the anchoring element comprising a first electrical lead coupled to the radially extending wire and a lead coupled to the patient whereby RF energy can be applied to the anchoring element during deployment and the at least one anchoring element forming a curved structure as it extends. Gough et al teaches a multiple antenna ablation apparatus that teaches it is known to provide an anchoring element (element 16 in Figure 1) with RF energy for ablating the tissue surrounding the anchoring device (see Columns 5-8, lines 34-54, specifically Column 8, lines 26-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of the current patent, to include RF energy sent to the anchoring element, as taught by Gough et al, for ablating the tissue surrounding the anchoring device.

Claims 44-48, 51, 66-70, and 73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 and 26 of U.S.

Patent No. 6,679,851 in view of Gough et al. The claims of the cited patent are similar to those of the current application except the claims do not disclose a radiation detector, an anchoring element comprising a first electrical lead electrically coupled to the at least one radially extending wire and a second electrical lead coupled to the patient, the tissue cutting member at the distal end of the shaft comprising an RF electrode, the electrode comprising an arcuate wire, and the electrode positioned in substantially the same plane as the longitudinal axis of the shaft. Gough et al teaches all of these limitations of the claims:

Regarding claims 44 and 66, Gough et al teaches it is known to provide a radiation detector at the distal end of the shaft for determining the extent of ablation, amount of ablation, whether or not further ablation is needed, and preventing non-targeted tissue from being destroyed (see Column 6, lines 35-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of the current patent, to include a radiation detector at the distal end of a shaft, as taught by Gough et al, for determining the extent of ablation, amount of ablation, whether or not further ablation is needed, and preventing non-targeted tissue from being destroyed.

Regarding claims 45 and 67, Gough et al teaches a multiple antenna ablation apparatus that teaches it is known to provide an anchoring element (element 16 in Figure 1) with RF energy for ablating the tissue surrounding the anchoring device (see Columns 5-8, lines 34-54, specifically Column 8, lines 26-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the claims of the current patent, to include RF energy sent to the anchoring element, as taught by Gough et al, for ablating the tissue surrounding the anchoring device.

Regarding claims 46-48, and 68-70, Gough et al teaches it is known to provide a cutting member at the distal end of the shaft comprising an RF electrode (either of elements 16 in Figure 6B) that can be viewed as an arcuate wire that lies in substantially the same plane as the longitudinal axis, for ablating the tissue surrounding the cutting member (see Columns 7-8, lines 37-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of the current patent, to include a cutting member that comprised an RF electrode, that consists of an arcuate wire that lies in substantially the same plane as the longitudinal axis, as taught by Gough et al, for ablating the tissue surrounding the cutting member.

Claims 52-54, and 74-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 and 26 of U.S. Patent No. 6,679,851 in view of Gough et al and further in view of Mulier et al (5431649). The claims of the cited patent are similar to those of the current application except the claims do not disclose an anchoring element extending through at least 540 degrees. Mulier et al teaches a helical coil electrode that is anchored into heart tissue (Figure 2, element 14), which serves to stabilize the catheter during R-F ablation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the claims of the current patent with a helical coil anchor

extending through at least 540 degrees, as taught by Mulier et al, to make the connection between the device and the tissue more stable.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al (5683384).

Regarding claim 37, Gough et al teaches an ablation apparatus comprising:

an elongated shaft (element 18, Figure 1),

a tissue cutting member at the distal end of the shaft (element 14 in Figure 1),

at least one anchoring element extending from a position at or near the distal end of the shaft (see element 16 in Figure 1),

a radiation detector at least a portion of which is disposed at or near the distal end of the shaft (see elements 24 in Figure 1).

Regarding claim 38, the anchoring element 16 in Figure 1 extends radially.

Regarding claim 39. see elements 16 in Figure 6B.

***Claim Rejections - 35 USC § 103***

Claims 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al in view of Ritchart et al (5810806). Regarding claims 25, 26, 29, and 30 Gough et al discloses the claimed invention except for the device detecting radiation from a radioactive material within the lesion site. Gough et al discloses a method including: providing an accessing tissue with an anchoring device having an elongated

shaft (around element 18 in Figure 3), at least one radially extending anchoring element (element 16 in Figure 3), and a tissue cutting member at the distal end of the shaft (element 14 in Figure 3), to ablate tissue (see Column 7, lines 26-65), extending at least one anchoring element, and securing the distal end of the device (see Column 8, lines 35-42). Ritchart et al teaches it is known to provide a slidable radiation detector and detecting radioactive material for location of a lesion in an area of soft tissue (see Columns 11-12, lines 34-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Gough et al to include a step of detecting radiation from a radioactive material, as taught by Ritchart et al, for location of a lesion in an area of soft tissue.

Regarding claim 27, the anchoring element is extended radially.

Regarding claim 28, see Gough et al Column 8, lines 40-41.

Regarding claim 31, Ritchart et al teaches it is known to provide a variety of different radiation detection means including a gamma camera (see Column 3, lines 3-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Gough et al to include a step of using a gamma camera for locating a site, as taught by Ritchart et al, because gamma cameras are well known in the art for determining a site with cancerous tissue.

Regarding claim 32, see Gough et al, Column 9, lines 49-54.

Regarding claim 33, the device as modified by Ritchart et al is capable of being used to cut and remove at least one sentinel lymph node.

Regarding claim 34, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mark provide a visible mark on the skin of the patient, to help assist the user of the device to locate the insertion point of the device.

Regarding claim 35, see Gough et al Column 7, lines 37-65.

Regarding claim 36, Gough et al shows arcuate shaped electrodes that are spaced distally from a distal extremity of the distal end of the cannula (see Figures 6A-C, and 7), the electrode can be viewed as any one of elements 16.

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al in view of Mulier et al. Gough et al discloses the claimed invention except for the device comprising an anchoring element comprising of a helical coil extending through at least 540 degrees. Mulier et al teaches a helical coil electrode that is anchored into heart tissue (Figure 2, element 14), which serves to stabilize the catheter during R-F ablation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the claims of the current patent with a helical coil anchor extending through at least 540 degrees, as taught by Mulier et al, to make the connection between the device and the tissue more stable.

***Response to Arguments***

Applicant's arguments filed December 22, 2005, with respect to the rejection(s) of claim(s) 25-48, 51-54, 66-70, 73-76 under Ritchart et al (5,810,806) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Gough et al (5,683,384) and a double patenting rejection with patent (6,679,851).

### *Allowable Subject Matter*

Claims 49, 50, 71, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

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